

Appl. No. : 09/549,131
Filed : April 13, 2000

REMARKS

Applicant herewith amends the method Claims 39, 40, 42, 43, 46, 48 and 49 by deleting the recitations regarding plasmapheresis or ultrafiltration. The amended method claims are dependent on generic method claims which recite those methods in the alternative, and the amended claims are not limited to a type of filtration but simply characterize the pore size or transmembrane flux of the fiber. It is submitted that basis for requiring election of species of Claims 42, 43, 48 and 49, has been eliminated, and that there is no reason for withdrawal of those claims from consideration.

The dependency of Claims 54-56 has been amended in view of cancellation of Claim 53.

Applicant has amended Claim 41 to recite the millimeters of Hg, thereby correcting the informality pointed out by the Examiner.

Nonelected apparatus Claims 1-29 have been cancelled, Applicant reserving the right to file a divisional application under 35 U.S.C. § 120 having priority based on the filing date of the original application. Claims 50, 51 and 53 have been cancelled as redundant in view of the language of Claims 30 or 32 on which they are dependent.

Applicant's method claims are rejected under 35 U.S.C. § 103(a) as unpatentable over Gorsuch et al. '224 in view of Angleraud et al. and EP '494. The rejection is a new rejection based on a new combination of references first presented in the Final Action to which this amendment is responsive. Accordingly, Applicant has not had the opportunity previously to discuss and distinguish this combination of references and the rejection based on the combination.

The Examiner is aware and admits that the primary reference, Gorsuch et al. '224, although teaching an *in-vivo* plasma separation method, does not teach an *in-vivo* plasma separation method utilizing a fiber as is recited in Applicant's claims. The Examiner looks to the secondary references, Angleraud et al. and EP '494, to supply the teachings lacked by the primary reference. It is submitted that the combination of references is improper under 35 U.S.C. § 103(a). It is also submitted that even if the references are combined, the combination fails to teach or suggest Applicant's invention under 35 U.S.C. § 103(a).

Gorsuch et al. '224 teaches a method of *in-vivo* plasma separation in which the separated plasma passes through the wall of hollow fibers from the outer surface to the interior lumen. However, the secondary references teach filtration through a fiber wall in the opposite direction.

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Angleraud et al. discusses the use of asymmetric membranes having one or two separating layers, a "separating layer" defined as being the dense surface layer, *see* col. 3, lines 18-20, and 55-58. Moreover, the membrane is used so that the separating layer is in physical contact with the biological fluid to be treated, *see* col. 4, lines 5-8. Where the membrane is formed into a hollow fiber, the fibers are used so that the fluid to be treated is circulated inside the hollow fiber, *see* col. 5, lines 2-6, and in such hollow fiber form, the dense separating layer is positioned on the inner wall of the fiber, *see* col. 5, lines 15-17. Thus, Angleraud et al. teaches the use of a hollow fiber having an asymmetric fiber wall structure in which the dense separating layer is on the inside of the fiber and teaches using such a fiber with the fluid to be treated in contact with the inner wall of the fiber. That is quite opposite a method of filtering plasma from blood by contacting blood on the outside of the fiber and passing the plasma from the outer surface to the inner lumen as taught by Gorsuch et al. It is also opposite Applicant's recited method wherein the plasma is separated from blood by passing the plasma through the fiber wall from the outer wall surface to the inner fiber lumen. Thus, because Gorsuch et al. and Angleraud et al. filter through the fiber in opposite directions, it is submitted that there is no incentive, no motivation, to even combine the references in an attempt to teach or suggest Applicant's method; *see In re Fritch*, 23 USPQ2d 1780; *In re Rouffet*, 47 USPQ2d 1453. Where is the incentive for selecting Angleraud et al. that teaches passing the fluid from the inner fiber wall to the outer surface, for modifying Gorsuch et al. that teaches just the opposite? It is submitted that there is no such required incentive or motivation, and thus the combination is clearly improper.

Moreover, even if the references are combined, such a combination fails to teach or suggest Applicant's method. The method recited in Applicant's claim separates plasma from blood in-vivo by passing the plasma from the outer wall to the inner wall using a fiber in which the mass density of the outer wall is greater than the mass density on the inner wall. The Angleraud et al. fiber separates components of a biological fluid by physical contact of the fluid with the separating layer on the inside of the fiber, *see* col. 4, lines 5-8, and col. 5, lines 5 and 6. Thus, modification of Gorsuch et al. with Angleraud et al. would require Gorsuch et al. to filter by passing plasma from the inner lumen to the outer surface. That is not a method described in Applicant's claims. Accordingly, the combination of Gorsuch et al. and Angleraud et al. fails to teach Applicant's method.

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Applicant is aware that Angleraud et al. teaches that the membrane may also comprise a separating layer on the outer wall, (col. 5, lines 17 and 18), in other words, two separating surfaces, unlike either Gorsuch et al. or that recited in Applicant's claims.

The secondary reference to EP '494 does not even teach or suggest plasmapheresis, but teaches fibers for industrial purposes such as water treatment in nuclear power stations and thermal power stations, removing muddiness in tap water, and in the fields of fermentation and food, as specifically disclosed on page 7, lines 35-38. The EP fibers are used by filtering from the inner surface to the outer surface as clearly described on page 5, line 2. Indeed, the effective membrane area is discussed in terms of the inner surface, *see* page 5, lines 2 and 3. Thus, the only method of using the EP fibers is in filtering from the inner surface to the outer surface, quite opposite the method recited in Applicant's claims and opposite the method disclosed in Gorsuch et al. Accordingly, it is submitted that the attempt to modify Gorsuch et al. by EP '494 is improper under 35 U.S.C. § 103(a) for the same reasons discussed above regarding Angleraud et al. Applicant must ask the Examiner what is the reason, suggestion or motivation that would lead one of ordinary skill in the art to combine a reference teaching filtering muddy water by filtering from an inner fiber lumen to the outer surface with a reference teaching filtering blood *in-vivo* from the outer fiber to the inner lumen? It is submitted that there is no motivation for combining the references as required by Federal Circuit case law as above cited. Moreover, even if the references are combined, how would such a combination result in Applicant's method? It would not. Applicant does not filter from the inner surface to the outer surface as is required by EP. The EP fibers have a critical inner structure of a "thick trunk," having a specific maximum diameter of 10-30 microns as discussed on page 3, lines 18-25. The EP fibers are used by filtering from the thick trunk inner surface, the surface having the greater pore diameter, to the outer surface having a smaller pore diameter. That is not the method recited in Applicant's claims.

The combination of references set forth by the Examiner in the Final Action is improper for the reasons set forth hereinabove. Moreover, the combination of references does not result in a method as recited in Applicant's claims for the reasons set forth hereinabove. Accordingly, it is submitted that the claims are in condition for allowance and notification thereof is requested.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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